K130532

MAY 3 0 2013

510(k) Summary of Safety and Effectiveness

SUBMITTER:	Covidien llc 60 Middletown Avenue North Haven, CT 06473 USA 203.492.5299 (T)
CONTACT PERSON:	Katherine Robertson Senior Regulatory Affairs Specialist
DATE PREPARED:	May 3, 2013
TRADE/PROPRIETARY NAME:	iDrive™ Ultra sterilization tray
PRODUCT CODE:	KCT
REGULATION NUMBER:	21 CFR 880.6850
COMMON/USUAL NAME:	sterilization tray
CLASSIFICATION NAME:	sterilization wrap
PREDICATE DEVICES:	PolyVac Surgical Instrument Delivery System (K012105) MetaPak Multi-Purpose Instrument Tray (K993535)
DEVICE DESCRIPTION:	The iDrive™ Ultra sterilization tray is an optional, over-the-counter, accessory to aid in storage and sterilization of the iDrive™ Ultra powered handle, Endo GIA™ adapter, iDrive™ battery insertion guide and iDrive™ Ultra manual adapter tool. It can simultaneously accommodate the following components: One (1) iDrive™ Ultra powered handle Two (2) Endo GIA™ adapters Two (2) iDrive™ battery insertion guides One (1) iDrive™ Ultra manual adapter tool The iDrive™ Ultra sterilization tray is an aluminum tray which is perforated to allow penetration of steam during steam sterilization. The tray can be processed through a minimum autoclave cycle of either 134°C for 3 minutes or 132°C for 4 minutes while being wrapped with a CSR wrap or within a sterilization container system.
INTENDED USE:	The iDrive™ Ultra sterilization tray, an over-the-counter accessory, is intended to provide storage for the iDrive™ Ultra powered stapling system during sterilization, storage and transportation within the hospital environment. The tray can contain at a maximum: one (1) iDrive™ Ultra powered handle, two (2) Endo GIA™ adapters, two (2)

iDrive™ battery insertion guides and one (1) iDrive™ Ultra manual adapter tool. The tray is intended to be sterilized by the following cycles:

Prevacuum Steam Cycles
132°C for 4 minutes
134°C for 3 minutes
Vacuum Dry Time: 20

TECHNOLOGICAL CHARACTERISTICS:

The iDrive™ Ultra sterilization tray is an optional accessory to aid in storage and sterilization of the iDrive™ Ultra powered handle, Endo GIA™ adapter, iDrive™ battery insertion guide and iDrive™ Ultra manual adapter tool.

MATERIALS:

The iDrive™ Ultra sterilization tray is not intended for patient contact. The iDrive™ Ultra sterilization tray is comprised of materials that are in accordance with ISO 10993-1.

PERFORMANCE DATA:

Testing has been performed and includes testing to the following standards:

- ANSI/AAMI ST77:2006
- AAMI TIR30:2003

SUBJECT AND PREDICATE COMPARISON:

	iDrive™ Ultra sterilization tray (subject device)	**PolyVac Surgical Instrument delivery system (K012105) (predicate device)**	**MetaPak Multi-Purpose Sterilization Tray (K993535) (predicate device)**
Indications	The iDrive™ Ultra sterilization tray (IDRVTRAY) is intended to provide storage for the iDrive™ Ultra powered stapling system during sterilization, storage, and transportation within the hospital environment. The tray can contain at a maximum: one (1) iDrive™ Ultra powered handle, two (2) Endo GIA™ adapters, two (2) iDrive™ battery insertion guides, and one (1) iDrive™ Ultra manual adapter tool. The tray is intended to be sterilized by the following cycles: Prevacuum Steam Cycles: 132°C for 4 minutes	Symmetry PolyVac delivery systems are intended for the protection, organization and the delivery to the surgical field of surgical instruments and/or other medical devices. Symmetry PolyVac are not designed to maintain sterility by themselves. They are designed to facilitate the sterilization process when used in conjunction with a wrapping material (FDA cleared sterilization wrap) or a specified filtered sterilization container system. Wrapping materials and sterilization containers are designed to allow air removal, steam penetration/evacuation (drying) and maintain the sterility of the internal	The MetaPak Instrument Tray is used for loading surgical instruments in order to conveniently organize, sterilize, transport and store the instruments between uses. The MetaPak Instrument Tray can be used in pre-vacuum steam and ethylene oxide sterilization cycles.

	134°C for 3 minutes Vacuum Dry Time: 20 minutes	components.	
Sterilization	Prevacuum steam	Prevacuum steam	Prevacuum steam
Material	Base – Aluminum Lid – Aluminum Base Inserts (Grommets) – Silicone Medical Grade Class 6	Base – Aluminum Lid – Aluminum Base Inserts (Grommets) – Silicone Medical Grade Class 6	Aluminum, Stainless Steel or aluminum/Radel combination.
Stacking	Do not stack cases and trays in the autoclave chamber. Stacking of cases and trays will adversely affect sterilization and drying effectiveness.	Stacking of delivery systems and overloading of the units will adversely effect sterilization and drying effectiveness. DO NOT STACK cases and trays in autoclave chamber.	Yes
Maximum Load Capacity	15 pounds	Full size case (~9x19x4) – 22 pounds	Unknown

The subject device and predicate devices are manufactured from identical metals, autoclavable, reusable and relative in dimensions, the subject device differs slightly from the predicate devices as the iDrive™ Ultra Sterilization Tray can only be sterilized via a prevacuum steam cycle while the PolyVac Surgical Instrument delivery system can be sterilized by prevacuum steam or gravity steam and the MetaPak Multi-Purpose Instrument Tray is sterilized by prevacuum steam or ethylene oxide. Additionally, the PolyVac Surgical Instrument delivery system and the iDrive™ Ultra Sterilization Tray cannot be stacked while the MetaPak Multi-Purpose Instrument Tray can be stacked.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 30, 2013

Ms. Katherine Robertson
Senior Regulatory Affairs Specialist
Covidien, Limited Liability Company
60 Middletown Avenue
NORTH HAVEN CT 06473

Re: K130532
Trade/Device Name: iDrive™ Ultra Sterilization Tray
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: II
Product Code: KCT
Dated: May 3, 2013
Received: May 6, 2013

Dear Ms. Robertson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Susan Runner, DDS, MA

Digitally signed by Mary S. Runner -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Mary S. Runner, 0.9.2342.19200300.100.1.1=1300087950
Date: 2013.05.30 15:47:49 -04'00'

Kwame Ulmer, M.S.
Acting Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K130532

Device Name: iDrive™ Ultra Sterilization Tray

Indications for Use:

The iDrive™ Ultra sterilization tray (IDRVTRAY) is intended to provide storage for the iDrive™ Ultra powered stapling system during sterilization, storage and transportation within the hospital environment. The iDrive™ Ultra Sterilization Tray is only intended to maintain sterility of the enclosed devices if it is used in conjunction with an FDA cleared sterilization wrap and has only been evaluated for a non-stacked configuration. The tray can contain at a maximum: one (1) iDrive™ Ultra powered handle, two (2) Endo GIA™ adapters, two (2) iDrive™ battery insertion guides and one (1) iDrive™ Ultra manual adapter tool. The tray is intended to be sterilized by the following cycles:

Prevacuum Steam Cycles
132°C for 4 minutes
134°C for 3 minutes

Vacuum Dry: 20 minutes

Prescription Use _____	AND/OR	Over-the-Counter Use X
(Part 21 CFR 801 Subpart D)		(21 CRF Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANTOHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Shani J. Smith
2013.05.30 14:54:05 -04'00'

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K130532